



Blood Hemoglobin Photometer Operating Manual



For use with instruments:
SN: XXXX-003XXX
Alkaline batteries
6 - 9 Volt DC Adapter

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General



Proprietary and established name:

Manufacturer: HemoCue AB, Ängelholm Sweden

HemoCue® B-Hemoglobin Microcuvettes and HemoCue® B-Hemoglobin Photometer.

The HemoCue® B-Hemoglobin system consists of disposable microcuvettes with reagent in dry form and a single purpose designed photometer. The microcuvette is used for measuring the sample, as a reaction vessel and as a measuring cuvette. No dilution is required. After conversion of the hemoglobin to azidemethemoglobin the reading takes place in the photometer, which measures the light absorption at two wavelengths. The photometer follows the reaction and presents the result only when the reaction has stopped. The photometer is calibrated at the factory against the cyanmethemoglobin (HiCN) method, which is the international reference method for the determination of the total hemoglobin concentration in blood.

Photometer, power adaptor and control cuvette are delivered in a carton. Open the carton on a stable surface and lift out the photometer and the accessories. The photometer may be powered by five type AA batteries. For installation of batteries see page 5. As with all electronic instrumentation, when using in extreme conditions, allow the photometer to come to ambient temperature (15-40° C, 59-104° F) before beginning analysis.

Intended Use

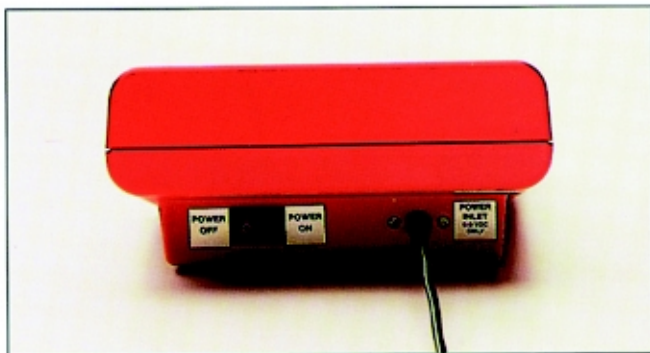
The HemoCue® B-Hemoglobin system is used for the quantitative determination of hemoglobin in blood using a specially designed photometer, HemoCue® B-Hemoglobin Photometer and specially designed microcuvettes, HemoCue® B-Hemoglobin Microcuvettes.

The HemoCue® B-Hemoglobin Photometer is only to be used together with HemoCue B-Hemoglobin Microcuvettes.

The use of any other device in the HemoCue® B-Hemoglobin Photometer except the HemoCue® B-Hemoglobin Microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.

The HemoCue B-Hemoglobin microcuvettes are for in vitro diagnostic use only.

Installation of the Photometer



At the back of the photometer is a power switch and a connector. Connect the power adapter to the "POWER INLET" and to the main power supply. Turn the switch to the "POWER ON" position.



The letters "Hb" should now be seen on the display. If not, check the connections to the photometer and to the main power supply. If the photometer is still not functioning after these checks, turn to "Troubleshooting Guide," page 16.



The cuvette holder, which is used to move the cuvette in and out of the photometer, has three positions:

Completely pushed in – measuring position.



Pulled out – loading position.



Completely withdrawn – for cleaning.

Battery Power

Underneath the photometer there is a lid covering the battery compartment which holds five type AA batteries.



Place five type AA batteries in the battery compartment observing the indication of polarity in the battery holder. Replace the lid. New batteries can operate continuously for approximately 100-150 hours. If battery powered, batteries can be readily conserved by switching off the photometer between measurements.

Note: When going from battery power to main power supply, turn off the photometer "POWER OFF", before connecting.



Control Cuvette



The control cuvette, which is an optical interference filter, must be read on each day of testing to verify that the calibration is stable, e. g. not changing from day to day. When checking the value received, it should not deviate from the assigned value on the control cuvette card more than ± 0.3 g/dl. If it does, turn to "Troubleshooting Guide," page 16. Page 7 gives a description of the use of the control cuvette.

As the control cuvette is specific to the photometer in which it has been assigned its value, make sure that the serial number on the control cuvette is the same as the serial number on the photometer.

The control cuvette should be kept in the box and protected from dust and dirt. The control cuvette may be cleaned with a 70–95% ethanol without additives or with isopropanol.

If the control cuvette is lost or damaged, contact your local distributor for replacement.

Checking the Photometer

Pull out the cuvette holder to the loading position. This point, which should not be exceeded, is easily established by paying attention to a distinct stop. The display shows the letters "Hb".



After approximately 15 seconds the indication "READY" appears on the display together with three flashing dashes. The photometer is ready for measurement.

Place the red control cuvette into the cuvette holder and push it into the measuring position.



The display now shows "MEASURING" and three fixed dashes. The photometer is measuring.



After approximately 10–15 seconds the photometer displays a value for the control cuvette. Compare this value to the assigned value on the enclosed control cuvette card. It should not deviate more than ± 0.3 g/dl. If it does, turn to "Troubleshooting Guide," page 16.



How to Perform a Blood Hemoglobin Determination



Capillary, venous or arterial whole blood may be used, see Sample Material page 12.

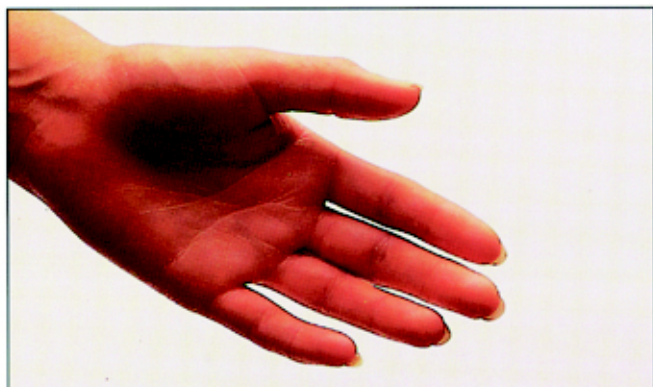
Put the switch at the back of the photometer to the position "POWER ON".

Pull out the holder to insertion position. This is noted by a **distinct stop which should not be exceeded**. The display shows "Hb" and after approximately 15 seconds "READY" with three blinking dashes.

Take the cuvette out of the container. **Reseal the container immediately**. Hold the cuvette opposite the filling end.

The microcuvettes are to be stored at room temperature (15-30° C, 59-86° F). Once opened, the microcuvettes are stable for three months, see page 12.

Capillary, Venous and Arterial



Capillary Samples

A capillary blood sample may be taken from any site, usually finger, ear or heel. Below, a technique for capillary finger sticks is described.

Make sure that the patient sits comfortably. The hand should be warm and relaxed. It is a good idea to heat cold hands in warm water before sampling. This increases the blood circulation. The patient's fingers should be straight but not tense, to avoid stasis.



For best result use the middle finger or the ring finger for sampling. Avoid fingers with rings for sampling. Clean the puncture site with disinfectant and allow it to dry completely or wipe off with a dry, lint free wipe.



Using your thumb, lightly press the finger from the top of the knuckle to the tip. This stimulates the blood flow towards the sampling point.

For the best blood flow and the least pain, sample at the side of the fingertip, not the centre. While applying light pressure towards the fingertip, puncture the finger using a lancet.



Wipe away the first two or three drops of blood. This stimulates the blood flow. If necessary, apply light pressure again, until another drop of blood appears. Avoid "milking."



Make sure that the drop of blood is big enough to fill the cuvette completely. Introduce the cuvette tip into the middle of the drop.



Fill the cuvette in one continuous process. Do NOT refill!



Wipe off the excess blood on the outside of the cuvette tip. Make sure that no blood is drawn out of the cuvette in this procedure. Note: If a second sample is to be taken from the same finger stick, it is important that this should be done immediately after the first sample has been taken. Wipe away the remains of the first sample and fill a second cuvette from a new drop of blood.



Filled cuvettes should be inspected for air bubbles, which, if present, can produce erroneously low readings. Small air bubbles around the edge do not influence the result.

If air bubbles are seen in the optical eye of the cuvette due to inadequate filling of blood, the cuvette should be discarded and another sample taken for analysis.

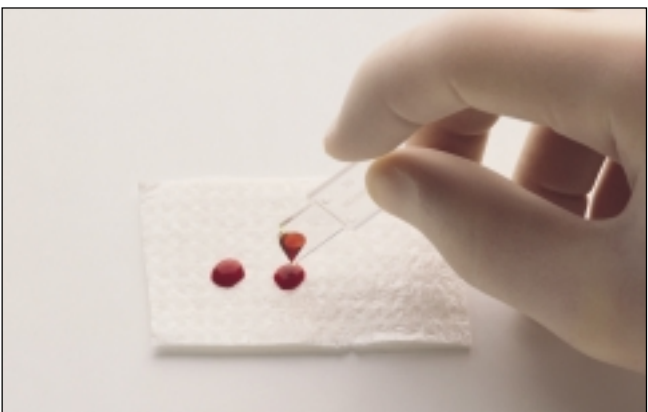
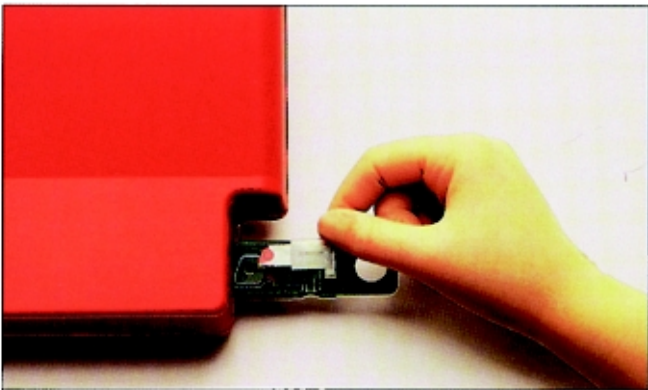
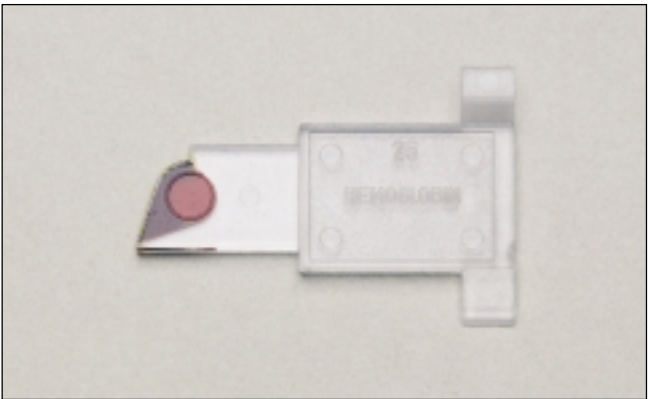
Place the filled cuvette into the cuvette holder immediately and push it into measuring position.

The filled cuvette should be analyzed immediately or at the latest 10 minutes after it has been filled.

After approximately 30–50 seconds the result is displayed. If "ERROR" code appears, turn to "Troubleshooting Guide," page 16.

Venous or arterial blood from tube or syringe.
The cuvette can also be filled with well mixed venous or arterial blood. Place a drop of blood (or use a pipette) onto a hydrophobic surface, for example a plastic film. Introduce the cuvette tip into the middle of the drop in such a way that the whole cuvette is filled in one step. Do NOT refill! For further handling of the cuvette, see above.
The cuvette can be filled directly from the tube, if the tube is not to be used for further analyses.

It should be noted that oxygenated blood which has been agitated over a long period produces oxygen pressure and viscosity at higher than normal levels.
The achievement of accurate results for blood in this condition requires analysis to be undertaken immediately after the cuvette has been filled.



Method

Vanzetti, G., J. Lab & Clin Med 67:1, 116 (1966).

Principle

Sodium deoxycholate hemolyzes the erythrocytes and hemoglobin is released. Sodium nitrite converts hemoglobin to methemoglobin which, together with sodium azide, gives azidemetemoglobin. The absorbance is measured at two wavelengths (570 and 880 nm) in order to compensate for turbidity in the sample.

HemoCue® B-Hemoglobin Cuvettes

Reagents

Sodium deoxycholate, sodium nitrite, sodium azide and non reactive ingredients.

Storage and Stability

The microcuvettes are to be stored at room temperature (15–30° C, 59–86° F). The microcuvettes are stable two years from the date of manufacture, in the unopened container. The expiration date is printed on each container. Once opened they are stable for three months.
Always keep the containers closed.

Calibration

The photometer is delivered calibrated against the hemiglobincyanide (HiCN) method which is the international reference method for the determination of the total hemoglobin concentration in blood. After the factory calibration, which is carried out at ≈ 14 g/dl, a maximum deviation of ± 0.3 g/dl is tolerated.

Sample Material

Capillary, venous or arterial blood may be used. Use EDTA, heparin or heparin/fluoride as anticoagulants preferably in solid form to avoid dilutional effect. Samples of blood collected with the recommended anticoagulants must be used within 24 hours. All specimens must be allowed to come to room temperature before use. Mix the samples for at least 10 times before use.

Quality Control

Control Cuvette

The function of the photometer must be checked on each day of testing by measuring the control cuvette. Values obtained should not deviate from the assigned value on the control cuvette card more than ± 0.3 g/dl.

Hemoglobin Controls, whole blood or hemolysate

If a quality control check of the total system i.e. photometer and microcuvette is desired, this may be performed by using whole blood or hemolysate with a given hemoglobin value. The blood control used should have a viscosity equal to that of normal blood. It is important that the control blood is stored, mixed and handled according to the manufacturers' instructions.

Note: Many whole blood or hemolysate controls that are available commercially contain additives that cause turbidity (cloudiness). As the photometer compensates for turbidity it can give lower hemoglobin value than those given for the control blood/hemolysate. Contact HemoCue Inc for availability of suitable controls.

Performance Characteristics

Linearity Range

0-23.5 g/dl

Values above 23.5 g/dl must be confirmed using a suitable laboratory method.

Expected Values

The following hemoglobin values are considered normal

Adult Males	13.0-18.0 g/dl
Adult Females	11.0-16.0 g/dl
Infants, after neonatal period	10.0-14.0 g/dl
Children, two years to teenage:	gradual increase to adult normals.

Due to the wide range of conditions (dietary geographical, etc) which affects normal values, it is recommended that each laboratory establish its own normal range.

Specifications

Power source

Transformer (UL file number 25Z4, E 112794)

Input 120 V AC (105-135) 60 HZ

Output 6 V DC 500 m A.

The photometer is protected through the self protected design of the transformer, which means that even if short circuited a hazardous event is remote.

The photometer has an internal voltage regulation with a built in current limiting function to protect the circuits in the photometer.

The photometer is equipped with a voltage monitor which will display Low Bat (only when powered by batteries). Regardless of power source, if the voltage is too low to guarantee an accurate measurement, Error code will be displayed and no measurement can be done.

Environmental condition

Operating temperature	15-40°C	59-104°F
Storage temperature	0-50°C	32-122°F

Hazards

The HemoCue B-Hemoglobin photometer is designed for stability, reliability and safety. The hazard associated with the electronic construction of the photometer is remote.

The involved reagents in the microcuvette are of low toxicity, but care should be taken to avoid ingestion. It should be noted that considerable care must be taken when working with any human blood product to eliminate the risk of exposure to communicable diseases that may be present in such blood product.

Limitations

Photometer: Use only at ambient temperature of 15-40°C (59-104°F)

Guarantee

The photometer carries a 24 month guarantee from the day of receipt.

Maintenance

The photometer is designed to work for a long period of time without any direct service. No preventive maintenance is needed for the electronic components of the photometer.

The cuvette holder should be cleaned after each day of use with alcohol or a mild soap solution after having been completely removed from the photometer. It can also be autoclaved. It is important that the holder is completely dry before being replaced in the photometer.

Technical Service

After the guarantee period, service/repair is made at fixed prices.

During the period of service/repair, a loaner photometer can be obtained from your distributor.

Technical Service 800-426-7256.

Spare Parts List

The HemoCue® Blood Hemoglobin Photometer is constructed with few parts. The following spare parts are available:

Power adaptor
Control Cuvette

References

Makarem, A. In Clinical Chemistry: Principles and Technics, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Eds., Harper and Row, Hagerstown, MD, 1974, pp. 1125—1147

Wallach, J. Interpretation of Diagnostic Tests, 1st ed., Little, Brown and Company, Boston, MA, 1970, pp. 6—7

Manufactured by
HemoCue AB, Ängelholm, Sweden

Troubleshooting Guide

If you are unable to resolve the problem by following this Troubleshooting Guide, please call HemoCue Inc Technical Services at 800-426-7256.

Symptom	Explanation	Action
The photometer shows "ERROR" and a digit code 900–908.	May be an occasional fault.	Turn off the photometer and switch it on again after 30 seconds. Take a new cuvette and repeat the measurement. If the problem continues, see specific error code below.
"ERROR" 900	Time for measurement is more than 300 seconds. 1. The cuvette is incorrect. 2. Printed circuit board is out of order.	1a. Check expiration date for the cuvettes 1b. Take a new cuvette and repeat the measurement. 2. The photometer needs service. Call Technical Service.
"ERROR" 901 or 902	1. Light intensity of the compensating light diode is too low. This is often the result of dirt (blood) in the light path. 2. The optronic unit is out of order.	1. Clean the optronic unit. Use e.g. the HemoCue Cleaner. Call Technical Service. 2. The photometer needs service. Call Technical Service.
"ERROR" 903	1. Disturbances on main power supply. 2. The optronic unit is out of order.	1. Change the wall socket or use battery power 2. The photometer needs service. Call Technical Service.
"ERROR" 905	1. Light intensity for one of the light diodes is too high.	1. The photometer needs service. Call Technical Service.
"ERROR" 906	1. Unstable blank value. The photometer might be cold.	1. Turn off the photometer and allow it to reach room temperature. If the problem continues, the photometer needs service. Call Technical Service.
"ERROR" 907	1. The battery power is too low.	1a. The batteries need to be replaced. Turn off the photometer and replace the batteries, five type AA. 1b. Use the main power supply.
"ERROR" 908	1. The absorbance is too high. Light blocking item in cuvette holder	1. Call Technical Service.
"ERROR" HHH	1. Measured value is above 25.6 g/dl.	
No characters on the display.	1. The photometer gets no power. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order.	1a. Check that the power adapter is connected to the main power supply. 1b. Check that the power adapter is securely connected to the photometer. 1c. Check that the cable is not damaged. 2. Turn off the photometer and replace the batteries, five type AA. 3. The photometer needs service. Call Technical Service.

Symptom	Explanation	Action
The display gives erroneous characters.	<ol style="list-style-type: none"> 1. The display is out of order. 2. The microprocessor is out of order. 	<ol style="list-style-type: none"> 1. The photometer needs service. Call Technical Service. 2. The photometer needs service. Call Technical Service.
The display shows "LOWBAT".	<ol style="list-style-type: none"> 1. The batteries need to be replaced. 2. If on main power, the optronic unit or the circuit board is out of order. 	<ol style="list-style-type: none"> 1. Turn off the photometer and replace the batteries, five type AA. 2. The photometer needs service. Call Technical Service.
The display does not switch from "Hb" to "READY" or from "READY" to "MEASURING".	<ol style="list-style-type: none"> 1. The magnet in the cuvette holder may be missing. 2. The reed switch in the optronic unit is out of order. 	<ol style="list-style-type: none"> 1. Call Technical Service. 2. The photometer needs service. Call Technical Service.
The control cuvette gives erroneous results.	<ol style="list-style-type: none"> 1. The control cuvette is cracked. 2. The control cuvette is dirty. 3. The optronic unit is dirty. 4. The control cuvette is upside-down in the cuvette holder. 5. Wrong control cuvette. 	<ol style="list-style-type: none"> 1. Order a new control cuvette. 2. Clean the control cuvette, see page 6. 3. Clean the optronic unit. Call Technical Service. 4. Check that the control cuvette is inserted correctly. 5. Check that the serial number of the control cuvette corresponds to the serial number of the photometer. 6. If the fault continues, call Technical Service.
Too high or too low values on controls.	<ol style="list-style-type: none"> 1. The cuvettes are too old or damaged, improper storage. 2. The optical eye of the cuvette is contaminated. 3. The control is not mixed well and/or not at room temperature. 4. Air bubbles in the cuvette. 5. The optronic unit is dirty. 6. The control is not suitable for the HemoCue system. 7. The calibration of the photometer has been changed. 	<ol style="list-style-type: none"> 1. Check the expiration date and storage of the cuvettes. 2. Remeasure the sample with a new cuvette. 3. Make sure that the control is mixed well and at room temperature. 4. Check the cuvette for air bubbles. Remeasure the sample with a new cuvette. 5. Clean the optronic unit. Call Technical Service. 6. See "Quality Control," page 13. 7. Measure the control cuvette. 8. See also instructions from the manufacturer of the control. 9. If the problem continues, call Technical Service.
Too high or too low values on patient samples in comparison with those expected.	<ol style="list-style-type: none"> 1. The cuvettes are too old or damaged, improper storage. 2. The optical eye of the cuvette is contaminated. 3. Air bubbles in the cuvette. 4. The optronic unit is dirty. 5. The calibration of the photometer has been changed. 	<ol style="list-style-type: none"> 1. Check the expiration date and storage of the cuvettes. 2. Remeasure the sample with a new cuvette. 3. Check the cuvette for air bubbles. Remeasure the sample with a new cuvette. 4. Clean the optronic unit. Call Technical Service. 5. Measure the control cuvette. 6. If the problem continues, call Technical Service.



Marketing and technical service in the USA:

HemoCue Inc

40 Empire

Lake Forest, CA 92630

Phone:

Order 800-323-1674

Technical

support 800-426-7256

949-859-2630

Fax

949-859-3066

BERGSTENS, HBG H. US.
900116 021023